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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/890,532 | 04/15/2002 | Kurt Burger | R.35252 | 3306 |

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| EXAMINER | |
|---|---|
| BEISNER, WILLIAM H | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1744 | |

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/890,532 | BURGER ET AL. | |
| | Examiner | Art Unit | |
| | William H. Beisner | 1744 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *15-29,31 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-29,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 15-23, 29, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser et al.(US 3,851,436).

The reference of Fraser et al. discloses a method of sterilizing vessels (2') wherein the interior of the vessel and the exterior of the vessel are exposed to a low-pressure plasma gas (See Figure 3 and related text).

With respect to claim 15, while the reference discloses (See Figure 3) that the plasma gas is separately introduced with respect to the interior and exterior of the vessel by using separate inlets (20 and 24), the instant claims differ by reciting that the interior and exterior of the vessels are sterilized at different times by selective excitation of the plasma.

First, whether the plasma of the reference of Fraser et al. is simultaneously introduced into the inlets (20 and 24) or sequentially introduced would have been obvious to of ordinary skill in the art while maintaining the required sterilization of the interior and exterior of the vessel. Use of separately controlled plasma sources for the interior and exterior of the vessel would have been obvious so as to optimize the sterilization requirements for each surface. Note the reference of Fraser et al. discloses that pressures below atmospheric are required for sterilization (See column 1, lines 54-62). Sequential sterilization of the interior and exterior of the vessel as discussed above would result in selective excitation of the gas introduced through port (20) verses that of port (24).

With respect to claims 16 and 20, the vessel is carried or placed within chamber (1) in which at least nearly a total vacuum can be produced (See vacuum pump (13). Plasma gas is provided to the interior of the vessel (2) by feed line (20) that is shielded from the chamber (1) and a gas pressure gradient is established and maintained in the interior of the vessel (2) such

that excited plasma gas is maintaining or contacts the interior of the vessel for a predetermined length of time.

With respect to claim 17, the gas pressure gradient is maintained by valve (15) and vacuum pump (15) for controlling the flow of plasma gas relative to the interior and exterior of the vessel (2).

With respect to claims 18, 29 and 30, the chamber (1) is initially evacuated (See column 1, lines 65-67).

With respect to claim 19, an independently control plasma gas can be provided on the exterior of the vessel (See Figure 3 and related disclosure).

With respect to claims 21-23, 31 and 32, sequential treatment of the interior of the vessel followed by an exterior treatment of the vessel as discussed with respect to claim 15 would result in pressure and sterilization conditions encompassed by the limitation of these claims.

5. Claims 24, 25, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser et al.(US 3,851,436) in view of Hoeck (US 4,544,529) or Schulte (US 2,501,193).

The reference of Fraser et al. discloses a plasma sterilization device that includes a chamber (1'), a conduit means (5") connected via feed line (5') with a gas supply (3) located outside the chamber (1'). The device includes a pump (13) connected to the chamber (1') and a plasma source (6',8') mounted on the outside of the chamber (1') and operable to excite plasma in the chamber (l').

With respect to claim 24, while the reference of Fraser et al. discloses a structure for supporting vessel (2) while holding the vessel within the chamber and also connecting the vessel

to the plasma gas source (See Figure 2), claim 24 differs by reciting that the vessel is supported on a cone with a leakage groove.

The reference of Hoeck (US 4,544,529) disclose a structure for holding a container while exposing the container to a sterilization gas wherein the holder includes a cone (15) that includes a groove forming member (13) such that gas can flow from the interior of the container to the exterior of the container (See Figure 1 and column 4, lines 1-26).

The reference of Schulte disclose a structure for holding a container while exposing the container to a sterilization gas wherein the holder includes a cone (8) that includes a groove forming member (11) such that gas can flow from the interior of the container to the exterior of the container (See Figure 2).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the cone or funnel structure of the reference of Hoeck or Schulte as a device for supporting and communicating the plasma gas with the interior of a vessel in the system of the primary reference when sterilizing vessels with a single opening for the known and expected result of providing an art recognized means for allowing a sterilization gas to contact the interior and exterior of a vessel to be sterilized.

With respect to claim 25, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to optimize the opening formed by the grooves for the known and expected result of ensuring that enough back-pressure is created within the container interior to ensure that the gas contacts the interior of the container a sufficient amount of time to ensure sterilization of the interior of the container.

With respect to claim 26, the use of endless chain conveyors is well known in the art for allowing a plurality of vessels to be run through

With respect to claim 27, both the references of Hoeck and Schulte disclose the use of the cones structures in combination with carriers or boxes (See element (3) of Hoeck and element (3) of Schulte) that include flange portions that allow the cones to be communicated with a source of sterilization gas.

With respect to claim 28, the device is capable of treating plastic or glass vessels.

6. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser et al.(US 3,851,436) in view of Hoeck (US 4,544,529) or Schulte (US 2,501,193) taken further in view of Schroeder et al.(US 6,328,928 or WO 98/30491).

The combination of the references of Fraser et al. with either Hoeck or Schulte has been discussed above.

Claim 26 differs by reciting that the system employs a chain link conveyor.

The reference of Schroeder et al. discloses that is it conventional in the art to employ endless chain conveyors for conveying a plurality of vessels with a sterilization system (See column 2, lines 10-14).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an endless chain conveyor with the system of the modified primary reference for the known and expected result of allowing a plurality of vessels to be passed through the sterilization system so as to avoid the need to manually open and close the chamber

between sterilization cycles. Use of a conveyor system would increase the efficiency and number of vessels that can be sterilized when compared to a manual operation.

***Response to Arguments***

7. With respect to the rejection of claims 15-32 under 35USC 112, second paragraph, Applicants' amendments to the claims are sufficient to overcome this rejection.

8. With respect to the rejection of claims 15-20 and 29 under 35 USC 102 over the reference of Fraser, Applicants' amendments to the claims and associated comments (See pages 9-13 of the response filed 8/3/05) are persuasive to overcome the rejection of record. However, he claims have been rejection under a new grounds of rejection over the reference of Fraser under 35 USC 103.

9. With respect to the rejection of claims 21-23 and 31 under 35 USC 103 over the reference of Fraser, Applicants argue (See pages 13-14 of the response filed 8/3/05) that the rejection is improper because the reference of Fraser does not teach a method for sterilizing vessels in which plasma sterilization in the interior region and the exterior region are performed at different times by selective excitation.

In response, for the same reasons as set forth in the new grounds of rejection under 35 USC 103 set forth above, the Examiner is of the position that the newly amended claims are prima facie obvious in view of the reference of Fraser. While the reference of Fraser does not specifically disclose contacting the interior and exterior of the vessel at different times, the

Examiner is of the position that whether the contact is simultaneous or sequential is not a patentable distinction in the absence of further positively recited claim language. Also, it is noted that the features upon which applicant relies (i.e., creation of differential pressures between the interior and exterior of the vessel using a passage that communicates the volumes of the interior and exterior of the vessel) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

10. With respect to the rejection of claims 24, 25, 27 and 28 under 35 USC 103 over the references of Fraser in view of Hoeck or Schulte and further in view of Schroeder, Applicants argue (See page 14 of the response dated 8/3/05) that the rejection is improper because none of the reference of Hoech, Schulte or Schroeder teaches that which is missing in Fraser.

In response, claims 24, 25, 27 and 28 are apparatus claims and are limited in the same manner as method claim 15. Note claims 24, 25, 27 and 28 merely recite a device that includes a chamber, a cone, conduits, pumps and plasma sources. Note statements of intended use carry no patentable weight in apparatus-type claims.

***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The reference of Ashman et al.(US 3,701,628) is cited as prior art which pertains to the generation of a low-pressure plasma gas within an article treatment chamber rather than generation exterior to the treatment chamber and subsequent introduction.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Beisner
Primary Examiner
Art Unit 1744

WHB